

AMENDED IN SENATE MARCH 24, 2010

SENATE BILL

No. 1071

Introduced by Senator DeSaulnier

February 17, 2010

An act to amend Section 11165 of, *and add Section 11165.05 to*, the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

SB 1071, as amended, DeSaulnier. Controlled Substance Utilization Review and Evaluation System.

Existing law provides for the electronic monitoring and reporting of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances pursuant to the Controlled Substance Utilization Review and Evaluation System (CURES) program.

This bill would *require the Department of Justice, beginning January 1, 2011, and annually thereafter, to determine and impose a fee on manufacturers and importers of controlled substances classified in Schedules II, III, and IV, as specified. The bill would require the State Board of Equalization to administer and collect the fee, as specified, and to deposit the fee in the CURES Fund established by the bill. The moneys in the CURES Fund would be available for expenditure, upon appropriation by the Legislature, only for reimbursement of the department for specified costs related to the CURES program. The bill would require that the fee imposed shall be consistent with all applicable legal requirements for imposing fees, as specified. The bill would make technical, nonsubstantive changes to these specified provisions relating to the CURES program.*

Vote: majority. Appropriation: no. Fiscal committee: ~~no~~-yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 *SECTION 1. The Legislatures finds and declares all of the*
2 *following:*

3 *(a) The CURES program is a valuable investigative, preventive,*
4 *and educational tool for law enforcement, regulatory boards,*
5 *educational researchers, and the health care community.*

6 *(b) Each year the CURES program responds to more than*
7 *60,000 requests from practitioners and pharmacists to (1) help*
8 *identify and deter drug abuse and diversion through accurate and*
9 *rapid tracking of Schedule II, III, and IV controlled substances,*
10 *(2) help practitioners make better prescribing decisions, and (3)*
11 *cut down on the misuse, abuse, and trafficking of prescription*
12 *drugs in California.*

13 *(c) The manufacture and importation of Schedules II, III, and*
14 *IV controlled substances have had deleterious effects on private*
15 *and public interests, including the misuse, abuse, and trafficking*
16 *in dangerous prescription medications resulting in injury and*
17 *death. The fee that is imposed by this bill on manufacturers and*
18 *importers of Schedules II, III, and IV controlled substances is to*
19 *be limited in amount and seeks to mitigate these effects of the drugs*
20 *by supporting the operation of the CURES program, which has*
21 *proved a cost-effective tool to help to reduce the misuse, abuse,*
22 *and trafficking of those drugs. There is a sufficient nexus between*
23 *the fee this bill imposes on manufacturers and importers of*
24 *Schedule II, III, and IV controlled substances and the deleterious*
25 *effects the bill would ameliorate through its funding of the CURES*
26 *program.*

27 *(d) It is the nature of these Schedule II, III, and IV controlled*
28 *substances that their addictive qualities and the ever present*
29 *market for their misuse and abuse pose inherent risks to public*
30 *health that must be systematically addressed, as by the CURES*
31 *program. Once these products are present in California, ad hoc*
32 *enforcement of conditions on distribution and criminal and civil*
33 *sanctions on downstream actors in the distribution system is an*
34 *extraordinarily costly, ineffective, and inefficient means to attempt*
35 *to control the misuse, abuse, and trafficking of these substances.*
36 *It is therefore appropriate for manufacturers and importers, which*
37 *benefit from the commercial markets for these inherently dangerous*
38 *products with knowledge of their potential for misuse and abuse*

1 *absent systematic tracking and monitoring, to pay for the*
2 *cost-effective CURES program.*

3 *(e) The Legislature declares that the imposition of a fee upon*
4 *the manufacturers and importers of Schedule II, III and IV*
5 *controlled substances by this act would not result in the imposition*
6 *of a tax within the meaning of Article XIII of the California*
7 *Constitution, because the amount and nature of the fee has a fair*
8 *and reasonable relationship to the adverse impact and burden*
9 *imposed by the manufacture and importation of Schedule II, III,*
10 *and IV controlled substances.*

11 **SECTION 1.**

12 **SEC. 2.** Section 11165 of the Health and Safety Code is
13 amended to read:

14 11165. (a) To assist law enforcement and regulatory agencies
15 in their efforts to control the diversion and resultant abuse of
16 Schedule II, Schedule III, and Schedule IV controlled substances,
17 and for statistical analysis, education, and research, the Department
18 of Justice shall, contingent upon the availability of adequate funds
19 *from the CURES Fund and from the Contingent Fund of the*
20 *Medical Board of California, the Pharmacy Board Contingent*
21 *Fund, the State Dentistry Fund, the Board of Registered Nursing*
22 *Fund, and the Osteopathic Medical Board of California Contingent*
23 *Fund, maintain the Controlled Substance Utilization Review and*
24 *Evaluation System (CURES) for the electronic monitoring of the*
25 *prescribing and dispensing of Schedule II, Schedule III, and*
26 *Schedule IV controlled substances by all practitioners authorized*
27 *to prescribe or dispense these controlled substances.*

28 (b) The reporting of Schedule III and Schedule IV controlled
29 substance prescriptions to CURES shall be contingent upon the
30 availability of adequate funds from the Department of Justice. The
31 Department of Justice may seek and use grant funds to pay the
32 costs incurred from the reporting of controlled substance
33 prescriptions to CURES. Funds shall not be appropriated from the
34 Contingent Fund of the Medical Board of California, the Pharmacy
35 Board Contingent Fund, the State Dentistry Fund, the Board of
36 Registered Nursing Fund, the Naturopathic Doctor's Fund, or the
37 Osteopathic Medical Board of California Contingent Fund to pay
38 the costs of reporting Schedule III and Schedule IV controlled
39 substance prescriptions to CURES.

(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, the dispensing pharmacy or clinic shall provide the following information to the Department of Justice on a weekly basis and in a format specified by the Department of Justice:

(1) The full name, address, and telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender and date of birth of the ultimate user.

(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

(4) NDC (National Drug Code) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) ICD-9 (diagnosis code), if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

1 *SEC. 3. Section 11165.05 is added to the Health and Safety*
2 *Code, to read:*

3 *11165.05. (a) The Department of Justice shall, beginning*
4 *January 1, 2011, and annually thereafter, impose a fee on*
5 *manufacturers and importers of controlled substances classified*
6 *in Schedule II, III, or IV in order to reimburse the department for*
7 *costs related to the CURES program which provides for the*
8 *electronic monitoring of the prescribing and dispensing of*
9 *controlled substances classified in Schedule II, III, or IV.*

10 *(b) The department shall impose a fee on manufacturers and*
11 *importers of controlled substances classified in Schedule II, III,*
12 *or IV that the department determines to be sufficient for, and*
13 *limited to, reimbursement of the department for the following*
14 *expenses:*

15 *(1) The cost of the administration of the CURES program as*
16 *required by this section and Sections 11165 and 11165.1.*

17 *(2) The cost of the maintenance of, and any improvements to,*
18 *the CURES program.*

19 *(3) The cost of education and outreach relating to the CURES*
20 *program.*

21 *(4) The cost of the investigation of abuses of the CURES*
22 *program.*

23 *(c) The State Board of Equalization shall administer and collect*
24 *the fee imposed by the department in compliance with the*
25 *following:*

26 *(1) The board may prescribe, adopt, and enforce regulations*
27 *relating to the administration and enforcement of this section,*
28 *including, but not limited to, regulations governing collections,*
29 *reports, refunds, and appeals relating to the fee imposed by this*
30 *section.*

31 *(2) The board may prescribe, adopt, and enforce emergency*
32 *regulations as necessary to implement the fee imposed by this*
33 *section.*

34 *(3) The imposed fee shall be due and payable from the*
35 *manufacturer or importer to the board on a quarterly basis, on or*
36 *before the last day of the second month following each calendar*
37 *quarter.*

38 *(4) Each manufacturer or importer of controlled substances*
39 *classified in Schedule II, III, or IV shall, on or before the last day*
40 *of the second month following each calendar quarter, pay the*

1 *imposed fee and file a return for the preceding quarterly period*
2 *with the board using electronic media, as prescribed by the board.*
3 *Returns shall be authenticated in a form or pursuant to methods*
4 *as may be prescribed by the board.*

5 *(5) The board may, to facilitate administration of the fee, require*
6 *that the payment of the fee and filing of the returns be made for*
7 *periods other than quarterly periods.*

8 *(d) The CURES Fund is hereby established in the State Treasury.*
9 *All fees imposed under this section, and any interest or penalties*
10 *imposed by the department or board with respect to those fees,*
11 *shall be paid to the board in the form of remittances payable to*
12 *the board. The board shall transmit any payment to the Treasurer*
13 *for deposit in the CURES Fund.*

14 *(e) Except for payments required to reimburse the board for its*
15 *administrative costs in collecting the fee imposed by this section,*
16 *all moneys deposited in the CURES Fund shall, upon appropriation*
17 *by the Legislature, be expended only for the purposes specified in*
18 *subdivision (b).*

19 *(f) Any fee imposed pursuant to this section shall be consistent*
20 *with all applicable legal requirements for imposing fees, including*
21 *the requirements set forth in Sinclair Paint Co. v. State Bd. of*
22 *Equalization (1997) 15 Cal.4th 866.*